

REMARKS

Upon entry of this Amendment and Response, claims 1-25 are pending. Claim 1 has been amended to more clearly define the subject matter of the claimed invention. Support for the amendment to claim 1 can be found throughout the specification and specifically at page 7 and pages 9-16, Examples 2-5. New claims 24 and 25 have been added. Support for new claims 24 and 25 can be found in the Specification at page 5, paragraph 16. No new matter has been added by the above amendment and additional claims.

Applicants note that the Office has stated on page 10 that additional references were found “to be next in line to be applied each time with at least two references.” The Office, however, did not address these references or apply them against the pending claims. In the event Applicants overcome the references relied on in the Office Action, it would appear that the Office intends to reject the pending claims based on these additional references. By doing so, the Office would be examining the pending application piecemeal, an act the M.P.E.P. states should be avoided. *See* M.P.E.P. § 707.07(g). Applicants, therefore, contend that it would be improper for the Office to rely on any of the references listed on page 10 of the pending Office Action in the event the Office’s pending rejections are overcome.

Applicants respectfully request reconsideration of the claim rejections in light of the following remarks.

REJECTIONS UNDER 35 U.S.C. § 103(a)

The Office has rejected claims 1-23 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,643,876 (“**Jacobs I**”), U.S. Patent No. 6,159,422 (“**Graves**”), EP 0 707 186

("Spencer"), EP 0 302 420 ("Jacobs II"), and EP 1 040 839 ("Wu")¹, alone and in combination. See Office Action at pp. 2-10.

According to the Office: "(1) It is conventional or well known in the art that hydrogen peroxide is biocidal agent. (2) It is conventional or well known in the art to use a chamber to contain and sterilize a material. (3) It is conventional or well known in the art to use a negative atmospheric pressure to enhance biocidal process before and/or after a material being contact[ed] with a biocidal agent. (4) It is conventional or well known in the art to use a plasma process to enhance a biocidal process. (5) It is conventional or well known in the art to ventilate the processed chamber to atmospheric pressure to safely open the processed chamber. (6) It is also conventional or well known in the art to sterilizing (sic) a material at less than 39°C." See *e.g.* Office Action at pp. 2-3.

The Office goes on to state that "[o]ne in the art has been working in and around with mixing and matching the above embodiments to find the best or most effect process to sterilize a material. Evidence can be seen in at least [one of Jacobs I, Graves, Spencer, Jacobs II and Wu]. . . . Since [Jacobs I, Graves, Spencer, Jacobs II and Wu alone or together] disclose, teach and suggest the main and essential embodiments of the claimed invention, the above claims are found to be rendered prima facie obvious by [Jacobs I, Graves, Spencer, Jacobs II and Wu]." *Id.* at pp. 3-9.

The Office concludes by stating that "[s]ince the processing steps and the material in the claimed invention are found to be conventional or well known in the art, a patentable (sic) may

¹ On page 8 of the Office Action, the Office cited Wu as U.S. Patent No. 4,643,876. U.S. Patent No. 4,643,876 is the Jacobs I reference. Applicants believe that the Examiner intended to cite Wu as EP 1 040 839, as done on page 9 of the Office Action. If mistaken, Applicants request clarification.

be obtained by objectedly (sic) showing or producing an unusual or unexpected result over the applied reference on the record. An argument with respect to working in or around with mixing and matching a processing step and/or material without producing or showing an unusual or unexpected result could be an obvious variant in the art, have and are given a little to no value. Accordingly, applicants are urged to early show or provide an unusual or unexpected result over the applied reference. An initial search has found about a dozen of references to be next in line to be applied.” *Id.* at pp. 10. Applicants respectfully traverse.

A. The Office Has Failed To Establish A *Prima Facie* Case Of Obviousness

Applicants contend that the Office has failed to meet the criteria necessary to establish a *prima facie* case of obviousness. Specifically, to establish a *prima facie* case of obviousness, the Office must show that there is a motivation to combine the references cited against the application, that there is a reasonable expectation of success, and that the prior art teaches all of the claimed limitations. *See* M.P.E.P. § 2143. Applicants respectfully submit that the cited references fail to disclose all of the recited claim elements.

To begin with, none of the cited references teach or suggest that the material being sterilized maintains its stability after sterilization. The specification of the present invention, however, discloses that even after two sterilization half cycles, the biological material maintains its stability. *See* Specification, Examples 2-5. Since none of the references, taken alone or in combination, teach or suggest all of the limitation of the pending claims, the Office has failed to establish a *prima facie* case of obviousness.

Additionally, Jacobs II discloses a sterilization process wherein the pressure inside the chamber is lowered two times. The final pressure used in the process disclosed by Jacobs II, however, is outside the pressure range claimed in claim 1, step (d). Jacobs II, therefore, fails to disclose each and every limitation of the pending claims.

Jacobs I, Graves, Spencer and Wu also fail to disclose each limitation of the claimed invention. Specifically, each reference fails to disclose a sterilization process wherein the chamber temperature is less than 39°C. For instance, in Jacobs I, adequate sterilization occurred at temperature of 56.9°C. *See* Jacobs I, col. 10, lines 6-27. The temperature of the plasma used in Graves is even higher and in the range of 100°C to 3000°C. Spencer does not disclose the temperature of the sterilization chamber. However, because the sterilization process disclosed in Spencer is substantially similar to the processes disclosed in Jacobs I and Graves a skilled artisan would conclude that the temperature of the chamber used in Spencer is at least 40°C. Finally, Wu does not address the temperature of the chamber used for sterilization. Instead, Wu discloses that the temperature of the “load” or material being placed in the chamber should reach temperatures of at least 30°C or more and preferably at least 35°C or more. *See* Wu, p. 3, lines 5-10; p. 7, lines 3-4. Since Wu is using a sterilization process similar to that disclosed in Jacobs I and Graves, one of skill in the art would conclude that the chamber temperature itself would reach at least 40°C. This temperature is outside the scope of claim 1 of the present invention.

Applicants respectfully submit that since each of the cited references, alone and in combination, fail to disclose each and every limitation of the pending claims, the Office has failed to meet its burden of establishing a *prima facie* case of obviousness.

B. The Presently Claimed Invention Achieves Unexpected Results

Without acquiescing to the Office's contention that it has established a *prima facie* case of obviousness, Applicants submit that the claimed invention, as disclosed in the specification, does exhibit unexpected results. Examples 4 and 6, which embody the claimed invention, demonstrate that at temperatures of 35°C (Example 4) and 32°C (Example 6), complete inactivation of *Bac. stearthermophilus* spores is achieved with only one half cycle. See Specification at pp. 13-15 and 17-18. Not only is sterilization achieved, but the biological materials undergoing sterilization maintain stability even after 2 half cycles. *Id.* In contrast, Jacobs I discloses that complete inactivation of spores did not occur until the temperature reached 59.6°C. See Jacobs I, col. 10, lines 6-27. Additionally, Jacobs II discloses that optimal results are achieved only when the chamber temperature is raised to 40°C. See Jacobs II at p. 6, lines 23-27. Because the prior art teaches that sterilization does not occur at temperatures lower than 40°C or at pressures from about 100 to 800 mtorr, it is unexpected that the claimed invention achieves sterilization, while allowing biological materials to maintain stability, at lower temperatures and pressures than those thought to be necessary by those skilled in the art. For this additional reason, the claimed invention is not obvious in light of Jacobs I and II, Graves, Spencer and Wu, either alone or in combination.

In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

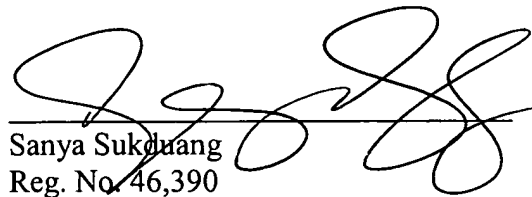
Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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